



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61B 17/39</b>	<b>A1</b>	(11) International Publication Number: <b>WO 95/20360</b> (43) International Publication Date: 3 August 1995 (03.08.95)
(21) International Application Number: PCT/IB94/00424 (22) International Filing Date: 14 December 1994 (14.12.94) (30) Priority Data: 08/189,523          31 January 1994 (31.01.94)          US (71) Applicant: VALLEYLAB, INC. [US/US]; 5920 Longbow Drive, Boulder, CO 80301 (US). (72) Inventor: SILVESTRINI, Thomas, A.; 1701 Las Trampas Road, Alamo, CA 94507 (US). (74) Agents: SPIEGEL, Allen, J. et al.; Pfizer Inc., Patent Dept., 235 East 42nd Street, New York, NY 10017 (US).		(81) Designated States: AU, CA, DE, FI, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>
(54) Title: <b>TELESCOPING BIPOLAR ELECTRODE FOR NON-INVASIVE MEDICAL PROCEDURES</b>		
(57) Abstract		
<p>Disclosed herein is a telescoping bipolar electrode (1) having an inner electrode (4) with an outer diameter (D4), length and outer side surface, such that up to the entire side surface is covered with an insulation sheath (5), which alternatively is fixed to the inner electrode (4) or is lengthwise adjustable with respect thereto, the inner electrode (4) and insulation sheath (5) together being slidably mounted within the inner space of an outer electrode (2) having an inner diameter greater than that of the inner electrode and its insulation sheath, an outer diameter (D2), thickness, length and an outer side surface area, the outer electrode (2) also having an insulation sheath (3) around its outer diameter (D2), covering up to the entire side surface area of the outer electrode (2), with the insulation sheath (3) around the outer electrode (2) being alternatively fixed to the outer electrode (2) or lengthwise adjustable with respect thereto. The bipolar electrode (1) is capable of being inserted into the human body through a body cavity or through the lumen of a vessel. At least one of the outer and inner electrodes is supplied with radio frequency energy from an external source (10). The bipolar electrode (1) is utilized to cut, desiccate or ablate neoplasms (12) in the body. In an alternative embodiment, the bipolar electrode (1) is configured such that the two component electrodes (2, 4) are arranged externally parallel to one another and are telescopically slidable relative to one another.</p>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

-1-

5                    TELESCOPING BIPOLAR ELECTRODE FOR NON-INVASIVE  
                         MEDICAL PROCEDURES

Background of the Invention

                 This invention relates to the field of bipolar electrodes, and particularly to bipolar  
electrode catheters in medical applications to supply radio frequency energy to  
10 desiccate or ablate a neoplasm, such as tissue or a tumorous mass in the body.

                 Conventional bipolar electrodes are constructed like a pair of tweezers, with  
each tweezer arm acting as one of the electrode poles. A neoplasm, such as tissue  
or a tumorous mass is removed using such an electrode by grasping the mass to be  
removed with the tweezers and passing a conducting current between the tweezer tips  
15 and through the mass, which is thereby desiccated or ablated. This type of bipolar  
electrode is generally large and bulky, requiring tweezers capable of spreading a  
substantial distance in order to be able to grasp a sizable mass. Accordingly, the  
conventional type of bipolar electrode is capable of being utilized only during an  
invasive procedure where a surgical opening is made that is sufficiently large to allow  
20 entry of the tweezer to the situs of the tissue or tumor to be removed, or in a  
non-invasive procedure in conjunction with an endoscope that is sufficiently large to  
allow deployment and operation of the tweezers from within the channel of the  
endoscope.

                 Because of this situation, the need for a streamlined, more compact form of  
25 bipolar electrode for neoplasm desiccation or ablation, capable of being introduced into  
the body non-invasively, either directly through relatively small natural body cavities, or  
by means of a catheter through the lumens of other vessels of the body, was  
recognized.

                 In order to meet this need, the bipolar electrode of the present invention was  
30 developed.

Summary of the Invention

                 The bipolar electrode of the present invention has a streamlined, compact shape  
which enables it to be non-invasively introduced into the body through even relatively  
narrow natural body cavities, or, in conjunction with a catheter, through the lumens of  
35 other vessels of the body, such as the arteries.

                 In a first preferred general embodiment of the apparatus of the present  
invention, the bipolar electrode is configured in an arrangement wherein the two  
component electrodes thereof are internally telescopable relative to one another. This

-2-

embodiment includes a outer electrode, which is preferably an open-ended cylinder, having an outer side surface, with an insulation sheath thereon, such that the sheath covers up to the entire outer side surface of the electrode; and, the outer electrode further having an inner space in which is slidably mounted a second, or inner electrode, which is preferably rod-shaped, having an outer diameter less than the inner diameter of the outer electrode, and a cylindrical shaft with a side surface, and a tip attached to the distal end of the shaft, and further having an insulation sheath thereon, covering up to its entire outer side surface, such that the overall diameter of the inner electrode and the insulation sheath thereon is still less than the inner diameter of the outer electrode.

10 In a second preferred general embodiment of the apparatus, the bipolar electrode is configured in an arrangement where the two component electrodes thereof are externally telescopable or slidable relative to one another. In this embodiment the second electrode, which can also have an insulation sheath thereon, covering up to the entire outer side surface of the electrode, is situated external to and slidably parallel with the first electrode, which can also have an insulation sheath thereon, covering up to the entire outer side surface of that electrode.

Both the first and second preferred general embodiments of the bipolar electrode of the present invention can have further specific alternative embodiments with respect to the details of their two principal component electrodes.

20 Brief Description of the Drawings

Fig. 1 is a view of a first preferred general embodiment of the distal end of a bipolar electrode according to the present invention, with the inner electrode in a retracted position.

25 Fig. 2 is a view of the bipolar electrode of Fig. 1, with the inner electrode in an extended position.

Fig. 3 is a view of the distal end of an alternative embodiment of the first preferred general embodiment of bipolar electrode according to the present invention, with a steerable flexible inner electrode shown in an extended position.

30 Fig. 4 is a view of yet another alternative embodiment of the first preferred general embodiment of bipolar electrode according to the present invention, wherein both the outer and inner electrodes have adjustable insulation sheaths.

Fig. 5 shows the distal end of a second preferred general embodiment of a bipolar electrode according to the present invention.

-3-

Fig. 6 shows the method of operation of a bipolar electrode of the present invention in the desiccation of a tumorous mass.

Detailed Description of the Invention

All embodiments of the first preferred general embodiment of bipolar electrode according to the present invention include a first, outer electrode and a second, inner electrode. The outer electrode is a substantially ring shaped, open ended cylinder, having an outer and inner diameter, a thickness, and a tubular side surface area, and an inner space. In one preferred embodiment the outer electrode is an open-ended cylinder. Either one of the outer and inner electrodes or both the outer and inner electrodes are separately surrounded by a sheath of insulating material which covers up to the entire side surface of the electrode. In another preferred embodiment, each electrode is separately surrounded by a sheath of insulating material that covers the entire side surface of the electrode. In alternative embodiments of bipolar electrodes according to the present invention, the first and second electrodes are configured to be adjacent to one another, rather than the second electrode being inside the first electrode. In such an arrangement, means are provided for slidably coupling the two electrodes to one another such that the first and second electrodes are capable of relative sliding movement with respect to one another.

Generally, in the most preferred embodiments, as described hereinafter, the outer cylindrical ring electrode is a cylindrical ring and has fixed dimensions of length, thickness, and inner and outer diameter. The cylindrical ring electrode forms an open ended cylinder with a tubular side surface and an inner space. The outer cylindrical ring electrode is fabricated from conventional metallic electrode material.

The outer cylindrical ring electrode is surrounded by a sheath of insulating material. In one embodiment, the insulating material forms a cylinder whose inner diameter is equal to the outer diameter of the electrode and is sealed at one end. The sheath is fixed to the metallic tubular side wall of the electrode and extends the full length of the cylinder, from the edge of its distal end to the edge of its proximal end, completely covering the face of the proximal end of the cylinder and leaving only an exposed metallic electrode surface, in the shape of a circular ring of width equal to the thickness of the metal from which the cylindrical ring electrode is fabricated, at the face of its distal end.

In an alternative embodiment, the sheath of insulation is not permanently attached to the metallic tubular side surface wall of the outer cylindrical electrode, but

-4-

Is instead slidably attached so that it can be slid back from the proximal end of the cylinder an adjustable length to leave a portion of the electrode side surface exposed.

In the most preferred embodiments, the inner electrode of the bipolar electrode is rod shaped and is slidably mounted in the space of the outer cylindrical ring electrode, such that the inner electrode "telescopes" with the outer electrode. The inner rod electrode has a solid cylindrical shaft portion terminating alternatively in a cylindrical or a streamlined rounded tip. The inner rod electrode has fixed dimensions of length and diameter. The size of the diameter of the rod is determined by the constraint that the overall diameter of the rod and an insulation sheath surrounding it, as will be described, be no larger than the inside diameter of the outer cylindrical ring electrode, so that the inner rod electrode and its insulation sheath may freely slide in the space of the outer cylindrical rod electrode. The inner rod electrode is also fabricated from conventional metallic electrode material.

The inner rod electrode is surrounded by a sheath of insulating material. In one embodiment, wherein the rod electrode has a cylindrically shaped tip, the insulation sheath completely encases the rod electrode except for a forward face of the tip where the metal front surface remains exposed. In this embodiment, the insulation sheath is fixed to the metallic side wall of the shaft of the inner rod electrode.

In an alternative embodiment, the sheath of insulation is not permanently attached to the metallic side surface of the shaft portion of the inner rod, but is instead slidably attached so that the insulation sheath can be slid back from the proximal end of the inner rod an adjustable length to leave a portion of the metallic side surface of the shaft of the inner rod electrode exposed.

Fig. 1 is an oblique view of the distal end of one preferred embodiment of a bipolar electrode 1 according to the present invention. The bipolar electrode 1 includes an outer cylindrical ring electrode 2 of thickness  $t_1$ , surrounded by a first insulation sheath 3 of thickness  $t_2$ . The overall bipolar electrode has an outer diameter  $D_1$  which includes the thickness of the outer insulation sheath. The cylindrical ring electrode itself has an outer diameter  $D_2$  and an inner diameter  $D_3$ , where the thickness of the metallic electrode  $t_1$  is equal to one half the difference  $D_2 - D_3$ . The inner space formed by outer cylindrical ring electrode 2 has a diameter equal to the inner diameter  $D_3$  of the ring electrode.

Inner rod electrode 4 is slidably positioned within the space of the outer cylindrical ring electrode. The inner rod electrode is alternatively fabricated either as

-5-

a tubular metallic rod closed at its front end or a solid metallic rod. The inner rod electrode has an outer diameter  $D_4$  which is smaller than the diameter of the space. The inner rod electrode is surrounded by a second insulation sheath 5 which is attached to the inner rod electrode and which separates the metallic outer surface of the rod from the metallic inner surface of the cylindrical ring electrode. The inner insulation sheath attached to the rod electrode has a thickness  $t_4$  equal to one half the difference  $D_3 - D_4$ . The combined diameter of the inner rod  $D_4$  and the thickness  $t_4$  of its insulation sheath, together, cannot exceed, and preferably is slightly less than the diameter  $D_3$  of the space of the cylindrical ring electrode to enable the rod electrode and its insulation sheath to freely slide back and forth in the space.

In alternative embodiments, the inner rod electrode and its insulation sheath are fabricated with a rounded, contoured tip, rather than a cylindrical shaped tip to minimize the possibility of the tip causing a perforation of the body cavity or vessel lumen in which the electrode is deployed, particularly when the rod electrode is extended beyond the forward edge of the cylindrical ring electrode.

Fig. 1 shows the bipolar electrode configured in the retracted mode, wherein the inner rod electrode and its insulation sheath are retracted inside the space of the cylindrical ring electrode, so that the tip of the rod electrode does not extend beyond a plane through the forward edge of the distal end of the cylindrical ring electrode. The bipolar electrode is deployed in this configuration to the situs of the neoplasm which is to be removed.

Fig. 2 is a side view of the bipolar electrode of Fig. 1, with the inner rod electrode and its insulation sheath shown in an extended position with the tip of the electrode and a portion of the shaft of the rod extended a distance beyond the forward edge of the outer cylindrical ring electrode. The bipolar electrode is placed in this configuration when it is to be energized for desiccation or ablation of a neoplasm.

In the embodiment of the bipolar electrode shown in Figs. 1 and 2, the first and second insulation sheaths are fixedly attached to the outer surfaces of the outer cylindrical ring electrode and the inner rod electrode, respectively. The insulating material completely covers the side surfaces of the cylindrical ring and the rod. The first insulation sheath around the outer cylindrical ring electrode extends to the forward edge of the cylindrical ring so that only a circular band of metal, equal in thickness to the thickness of the cylindrical ring electrode itself,  $t_1 = (D_2 - D_3)/2$ , remains exposed in

-6-

a plane passing through the forward face of the electrode, perpendicular to the axial direction of the electrode.

In the case of the inner rod electrode which has a cylindrically shaped tip, the second insulation sheath around the inner rod electrode also extends to the forward  
5 edge of the cylindrical rod so that only a circle of metal, of the same diameter as the rod electrode itself,  $D_3$ , remains exposed in a plane passing through the forward face of the electrode, perpendicular to the axial direction of the electrode.

In the case of the inner rod electrode which has a parabolically contoured tip, in one alternative embodiment the insulation sheath covers substantially the entire tip,  
10 leaving only a circular dot of exposed metal at the far point of the tip. In another alternative embodiment, the entire parabolically contoured tip is left uncovered of insulation, leaving the metallic surface of the electrode tip exposed; in this embodiment, only the cylindrical shaft portion of the rod electrode is insulated.

In yet other alternative embodiments of the bipolar electrode according to the  
15 present invention, the first and/or second insulation sheaths are adjustably, rather than fixedly, attached to the outer surfaces of the outer cylindrical ring electrode and the inner rod electrode, respectively. In these embodiments, the insulation sheaths are capable of being retracted from the proximal ends of the electrodes an adjustable distance along the length of the electrodes to expose a portion of the metallic side  
20 surfaces of the electrodes at their distal ends.

The distance to which the insulation sheaths are retracted to expose additional side surface area of the electrodes is determined by considerations of the size and shape of the neoplasm to be removed and the energizing mode of the electrodes, either for desiccation or ablation. It is important that good contact between the  
25 electrode surface and the neoplasm be established in order for application of the radio frequency energy to be effective. Moreover, greater surface contact may be required when operating in desiccation mode than for ablation mode.

Fig. 3 shows another preferred embodiment of a bipolar electrode according to the present invention wherein both the first and second insulation sheaths, on the outer  
30 surfaces of the outer cylindrical ring electrode and the inner rod electrode, respectively, are adjustably attached. The bipolar electrode 1 is shown in an extended operational configuration, with inner rod electrode 4 extended a total distance  $L'$  beyond the exposed metallic forward face of the outer cylindrical ring electrode 2. In addition, both electrodes are shown having their insulation sheaths retracted to expose additional



-7-

electrode side surface area, as for the ablation mode of operation. Thus, the first insulation sheath 3 surrounding the outer cylindrical ring electrode 2 is retracted a distance  $L_1$  from the forward face of the electrode to expose side surface area 2a of the electrode. Similarly, the second insulation sheath 5 surrounding the inner rod electrode 4 is retracted a distance  $L_3$  from the forward face of the electrode to expose side surface area 4a of the electrode. The insulation sheath is advanced an adjustable length  $L_2$  beyond the forward face of the outer cylindrical ring electrode. The distance  $L_2$  by which the insulation sheath is advanced, plus the distance  $L_3$  by which the front of the insulation sheath is retracted from the face of the inner rod electrode total  $L'$ , the axial distance between the tip of the inner rod electrode and the face of the cylindrical ring electrode.

In some situations, the neoplasm to be removed may be so irregularly shaped that sufficient contact between the electrode and the tissue cannot be attained even when the insulation sheath is retracted from the inner rod electrode to expose additional electrode side surface area. In such instances, it is desirable to have a flexible inner rod electrode and insulation sheath so that the rod electrode, once extended linearly beyond the forward face of the cylindrical ring electrode, can be bent to a position whereby the inner rod electrode surface area more closely adheres to the irregular shape of the neoplasm. The flexible inner rod electrode is capable of being extended beyond the forward edge of the face of the cylindrical ring electrode and bent such that the rod electrode takes an arcuate shape and extends outside an extension of the circumference of the first insulation sheath, forming an angle with a central axis through the center of the cylindrical ring electrode. The flexible inner rod electrode of this embodiment is steerable from the proximal end of the bipolar electrode by means of a control wire.

Fig. 4 shows a bipolar electrode 1 of the type with a flexible steerable inner rod electrode 4. The inner rod electrode 4, together with its insulation sheath 5, are in an arcuately extended position beyond the forward edge of the face of the cylindrical ring electrode 2 and its insulation sheath 3. The inner rod electrode is adjustably extended an arcuate length  $L_1$  beyond the forward edge of the cylindrical ring electrode. The center line through the tip of the inner rod electrode intersects the center line through the outer cylindrical ring electrode at a variable solid angle  $\Theta$ , which is a function of the degree of curvature imparted to the rod electrode.

-8-

The embodiment of the bipolar electrode according to the present invention which incorporates a flexible, steerable inner rod electrode can also be fabricated so that the insulation sheath on the inner rod electrode and/or the insulation sheath on the outer cylindrical ring electrode are slidably adjustable to expose additional metallic electrode side surface area on one or both electrodes. The features of being able to position the inner rod electrode in an arcuately shaped configuration, together with being able to adjust the insulation sheaths on at least the inner rod electrode or both the inner rod and outer cylindrical ring electrodes, provides great flexibility in utilizing the bipolar electrode of the present invention to remove neoplasms of greatly varying size and shape.

Both the outer cylindrical ring electrode and the inner rod electrode are connected to a radio frequency (RF) generator which supplies RF energy to each electrode for desiccating or ablating a neoplasm.

In the second preferred general embodiment of bipolar electrode according to the present invention, the two principal component electrodes are externally configured relative to one another and are telescopically slidable relative to one another.

Fig. 5 shows the distal end of the second preferred general embodiment of a bipolar electrode 1 according to the present invention wherein the second electrode 4 and the second insulation sheath 5 are positioned externally parallel to the first electrode 2 and the first insulation sheath 3 and are telescopically slidable in relation thereto. According to this embodiment, the first and second electrodes can be fabricated to have substantially the same outer diameters, since it is not necessary for the first electrode to be fabricated as a cylindrical tube of larger diameter than the second electrode to accommodate the second electrode inside. According to this embodiment, both electrodes can be fabricated as solid rods. Both electrodes can be provided with insulation sheaths which can be fixed or slidable with respect to its electrode. In this embodiment, the two electrodes are slidably coupled with respect to one another by means (not shown) which allows relative movement of the second electrode and its insulation sheath with respect to the first electrode and its insulation sheath. Because the outer diameter of the first electrode can be fabricated smaller than in embodiments wherein the second electrode is positioned inside the first electrode, this embodiment with the two electrodes positioned externally parallel to one another can be fabricated to have an equivalent overall outer diameter ( $D_5$ ) comparable to an embodiment with the second electrode positioned inside the first electrode.

-9-

The bipolar electrode of the present invention, because of its streamlined and compact configuration, is ideally suited for medical applications, particularly for the removal of neoplasms such as tissue or a tumorous mass from relatively inaccessible parts of the body. The bipolar electrode of the present invention, because of its compact size, has the advantage over conventional bipolar electrodes in that it can be readily used non-invasively to bring the RF energy supplying electrodes to the situs of the mass to be removed either by inserting the electrode through a relatively small natural body cavity or through utilization in conjunction with a catheter, ahead of which the electrode of the present invention is attached, by passing the catheter and bipolar electrode through the lumen of a vessel of the body, such as an artery, to the situs of the mass to be removed. As used herein, the term non-invasively means not requiring a large surgical opening, and includes procedures wherein a small puncture type incision of the body is required through which the bipolar electrode is inserted.

A bipolar electrode according to the present invention is utilized to remove a neoplasm by non-invasively inserting the bipolar electrode into the lumen of a vessel of the human body, with the electrode in a fully telescoped configuration, that is, with the inner rod electrode and its insulation sheath fully retracted within the space of the outer cylindrical ring electrode and its insulation sheath, as shown in Fig. 5 and advancing the bipolar electrode through the lumen to the vicinity of the neoplasm. The inner rod electrode is then slid forward to advance its tip a distance beyond the forward edge of the distal end of the outer cylindrical ring electrode. The extent of contact between the elements of the bipolar electrode and the neoplasm is determined by the mode of neoplasm removal in which the bipolar electrode is to be used. Thus, in certain instances where the bipolar electrode is used for simple cutting of a small neoplastic mass, minimal contact between the tip of the inner rod electrode and the mass is usually sufficient. When the mass is larger, greater contact may be required, and if the mass is deep, the inner rod electrode may be utilized in a lance-like manner to pierce the neoplasm. In this instance, in order to afford greater contact between electrode surface and the mass, the embodiment of the bipolar electrode in which the insulation sheaths covering the rod and ring electrodes are slidably adjustable is preferably used, with at least the insulation sheath over the inner rod electrode being retracted to expose a portion of the total side surface of the shaft portion of the rod, in addition to the tip. The exposed portion of the side surface of the shaft of the inner rod electrode contacts the neoplastic mass as the inner rod electrode pierces the mass.

-10-

In this procedure, the mass is cut away by the rod electrode tunneling its way through. While operating in this manner, the exposed forward surface of the outer cylindrical ring electrode may also be brought to bear on the proximal part of the neoplastic mass to further increase the amount of electrode-mass contact surface available for cutting.

In situations where the bipolar electrode is used in the ablation mode to completely vaporize a neoplastic mass, the available area of the electrode elements and the mass is made small. This is accomplished by also adjusting the insulation sheath from the inner and outer cylindrical electrodes as required.

Where the neoplastic mass to be removed is relatively thick, the inner rod electrode with its insulation sheath retracted is inserted through the mass so that the exposed electrode surface of the tip is against the distal end of the mass, the exposed shaft portion of the rod electrode contacts the mass throughout, and the exposed electrode surface at the end of the outer cylindrical ring electrode contacts the proximal end of the neoplastic mass.

For all cases, after the electrode surface is optimally placed in contact with the neoplastic mass, radio frequency energy is applied to one of the contacting electrodes and is allowed to pass from the energy-supplied electrode through the neoplastic mass, to the other electrode, thereby cutting or ablating it depending on the amount of energy utilized.

When the cutting or ablating process is completed, the application of radio frequency energy is terminated and the inner rod electrode and its insulation sheath are again retracted into the space of the outer cylindrical ring electrode. The procedure is completed by withdrawing the retracted bipolar electrode through the lumen of the vessel and withdrawing it from the body.

Fig. 6 shows the use of a bipolar electrode according to the present invention in the removal of a brain tumor. Bipolar electrode 1 is inserted, in the retracted configuration, through a small incision in the skull and is advanced to the site of the tumorous mass 12, which has been identified and located by X-ray or other conventional diagnostic technique. The electrode is positioned in proximate contact to the forward edge of the mass and the electrode is telescoped so that the inner rod electrode 4 pierces the mass. The inner rod electrode 4 is then advanced through the mass until the leading edge of its tip is in contact with the far edge of the mass. In order to maximize the electrode surface area in contact with the mass, the inner rod

-11-

electrode is advanced through the mass. The forward edge of the outer cylindrical ring electrode 2 is positioned in abutting contact with the forward edge of the mass. Radio frequency energy is then supplied to the inner rod electrode from generator 10 via wire 7. A current flows from the inner rod electrode through the mass, dessicating it, and  
5 Is then collected at the outer ring electrode, flowing back through wire 6 to complete the circuit.

The foregoing examples of embodiments of a bipolar electrode and its method of use according to the present invention are representative and are not meant to be limiting. Other embodiments, areas of application and methods of use of the bipolar  
10 electrode of the present invention, within the scope of the claims appended hereto, will be evident to those skilled in the art. Other embodiments of a bipolar electrode within the scope of the claims include, for example, those with outer and inner electrodes having other shapes than the outer cylindrical electrode and inner rod electrode of the preferred embodiments described in detail above.

15

-12-

CLAIMS

1. A bipolar electrode (1) comprising:
  - a first electrode (2) with a distal end and a proximal end, having dimensions of length, thickness, and outer diameter, and further having an outer side surface;
  - 5 a first layer of insulation (3) attached to up to the entire outer side surface of the first electrode;
  - a second electrode (4), with a distal end and a proximal end, having dimensions of length and outer diameter, and further having an outer side surface;
  - a second layer of insulation (5) attached to up to the entire outer side surface
  - 10 of the second electrode;
  - characterized by said first electrode (2) and said second electrode (4) being configured with respect to one another in a manner selected from the group consisting of: (i) having the second electrode (4) slidably positioned inside the first electrode (2), wherein the first electrode (2) has an open-ended tubular shape with an inner diameter,
  - 15 and an inner space, such that the total outer diameter of the second electrode (4) and the second layer of insulation (5), taken together, is not greater than the inner diameter of the first electrode (2); and (ii) having the second electrode (4) slidably positioned externally parallel to the first electrode (2), wherein means for slidably externally coupling the first electrode (2) and the second electrode (4) to one another is further
  - 20 provided; and
  - a radio frequency generator (10) for supplying radio frequency energy to at least one of the first electrode (2) and the second electrode (4).
2. The bipolar electrode (1) according to claim 1 further characterized in that both the first electrode (2) and the second electrode (4) are exposed only at the
- 25 respective distal ends thereof.
3. The bipolar electrode (1) according to claim 1 further characterized in that when the second electrode (4) is slidably positioned inside the first electrode (2), the second electrode (4) with the attached second layer of insulation (5) is slidable within the first electrode (2) an adjustable distance beyond the distal end of the first
- 30 electrode (2).
4. The bipolar electrode (1) according to claim 3 further characterized in that the second electrode (4) is arcuately flexible in order to be steerable, to a position forming a solid angle ( $\Theta$ ) with respect to a common central axis running through the first electrode (2) and the second electrode (4), when in a retracted position within the

-13-

first electrode (2), with the distal end of the second electrode (4) extending outside an extension of the circumference of the first electrode (2).

5        5.        The bipolar electrode (1) according to claim 1 further characterized in that the first layer of insulation (3) attached to the outer side surface of the first electrode (2) is slidably adjustable to expose a portion of the outer side surface area of the first electrode (2).

10       6.        The bipolar electrode (1) according to claim 1 further characterized in that the second layer of insulation (5) attached to the outer side surface of the second electrode (4) is slidably adjustable to expose a portion of the side surface area of the second electrode (4).

15       7.        The bipolar electrode (1) according to claim 1 further characterized in that the first layer of insulation (3) attached to the outer side surface of the first electrode (2) is slidably adjustable to expose a portion of the side surface area of the first electrode (2) and the second layer of insulation (5) attached to the outer side surface of the second electrode (4) is slidably adjustable to expose a portion of the side surface area of the second electrode (4).

20       8.        The bipolar electrode (1) according to claim 1 further characterized in that when the second electrode (4) is slidably positioned externally parallel to the first electrode (2), the second electrode (4) with the attached second layer of insulation (5) is slidable relative to the first electrode (2) an adjustable distance beyond the distal end of the first electrode (2).

9.        The bipolar electrode (1) according to claim 1, further characterized in that the first electrode (2) is a cylindrically shaped tube.

25       10.       The bipolar electrode (1) according to claim 1 further characterized in that the second electrode (4) is a rod.

11.       The bipolar electrode (1) according to claim 1, further characterized in that when the first electrode (2) and the second electrode (4) are slidably positioned externally parallel to one another, both the first electrode (2) and the second electrode (4) are rods.

30

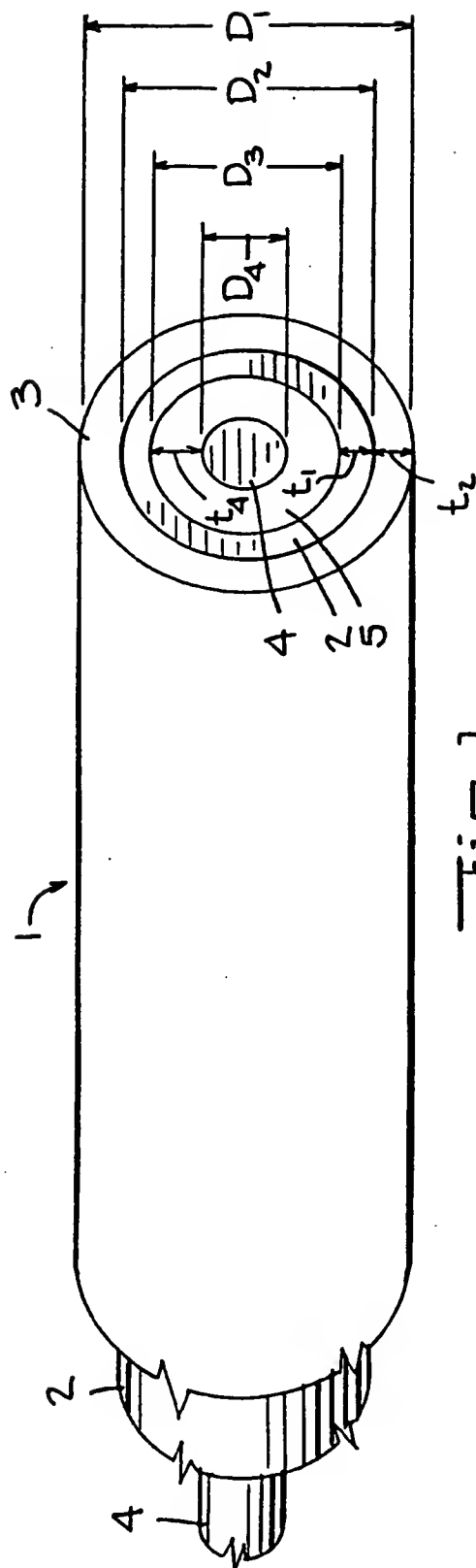


Fig. 1.

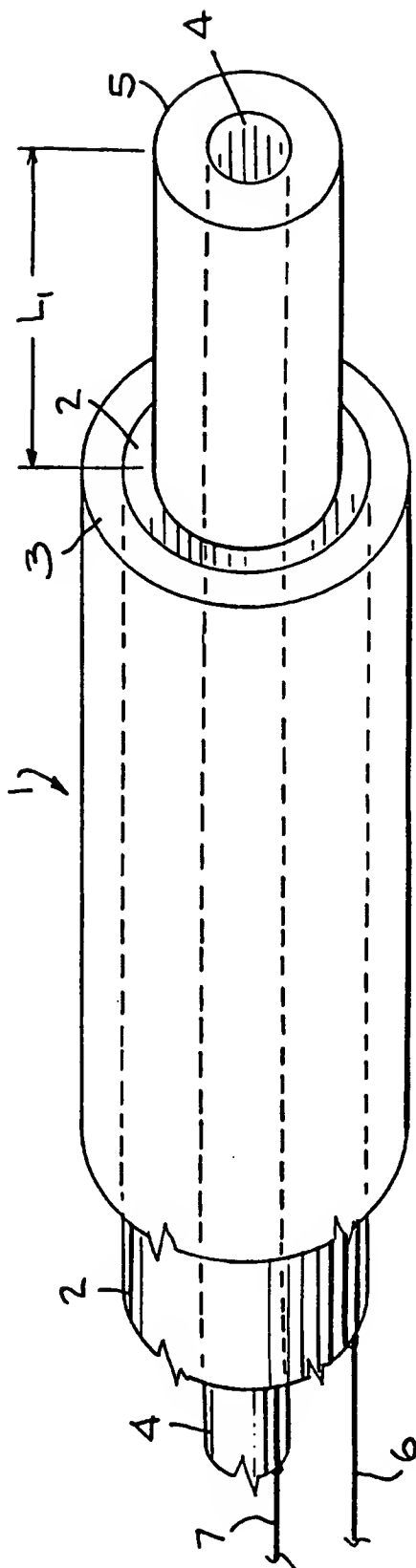
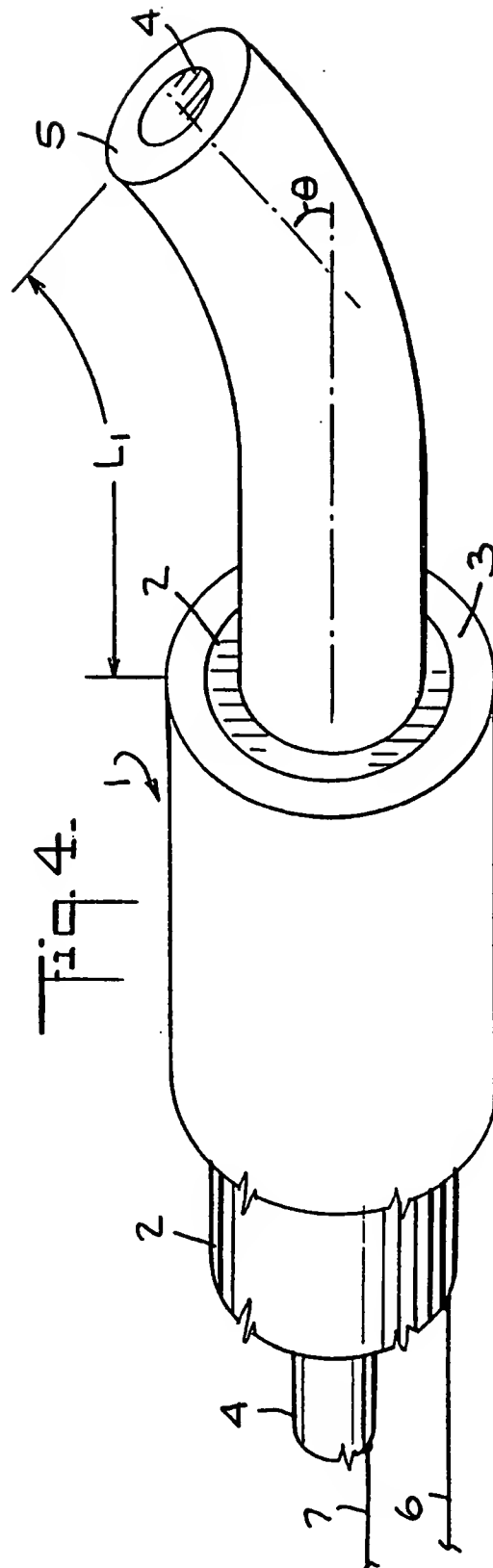
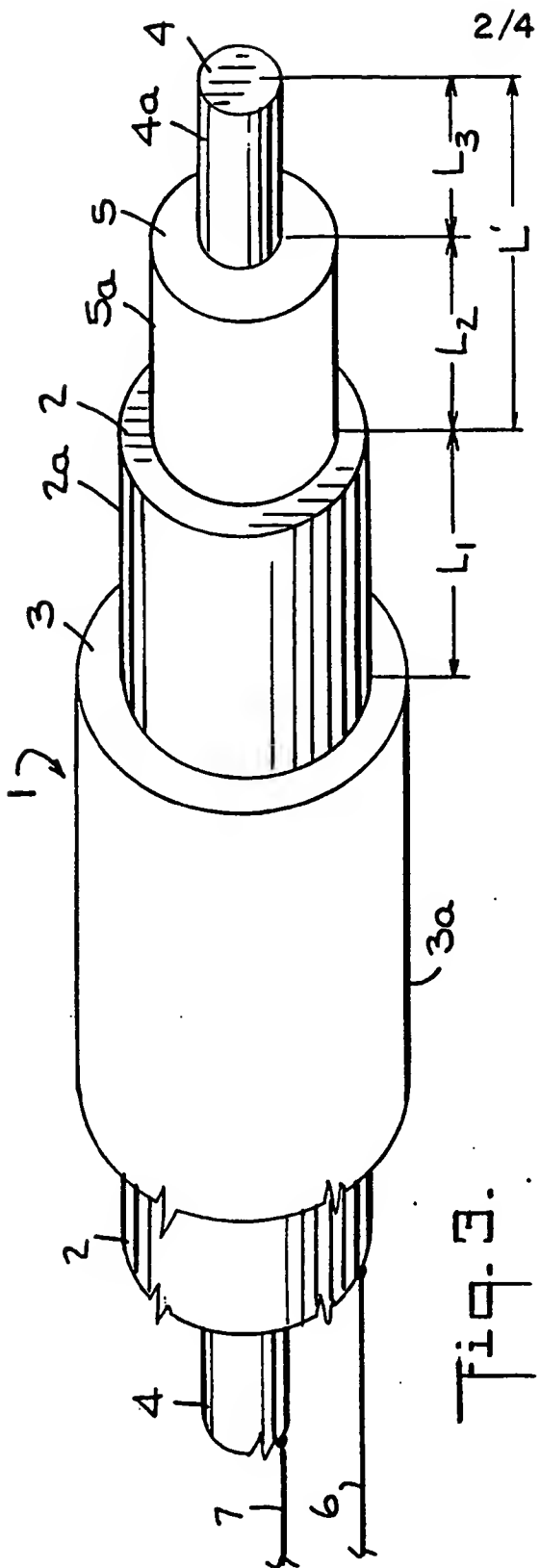
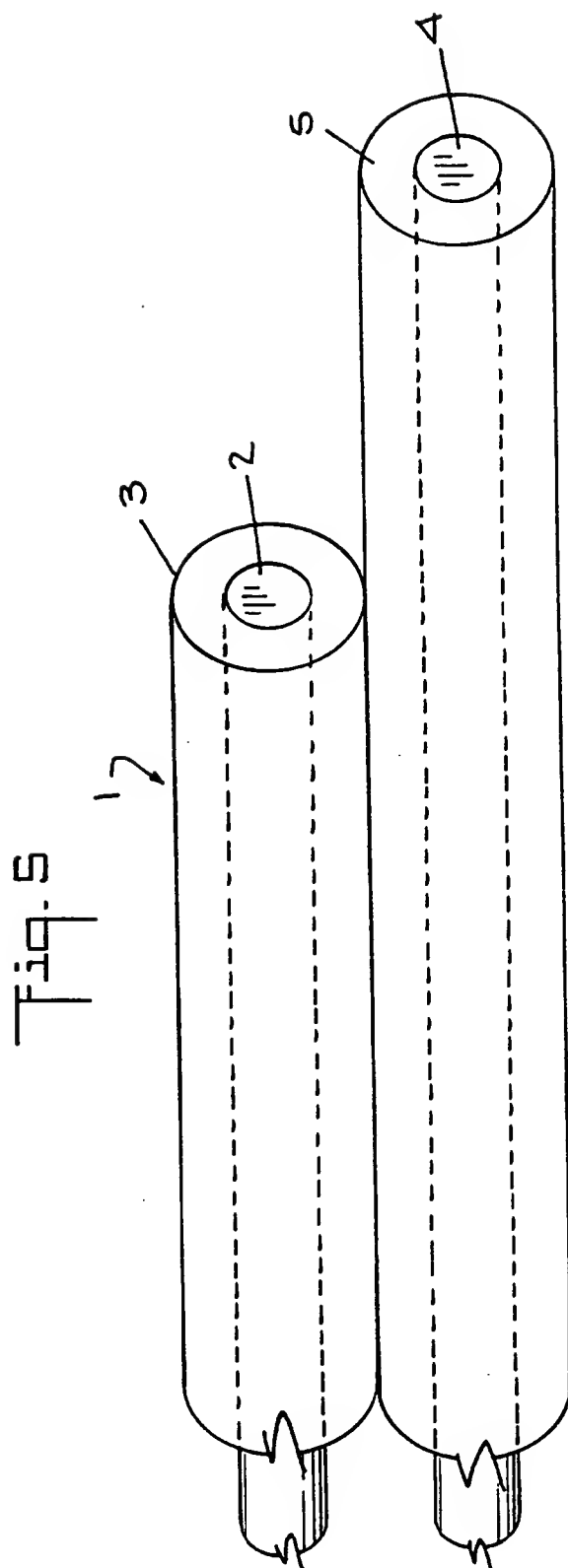


Fig. 2.





3/4



4/4

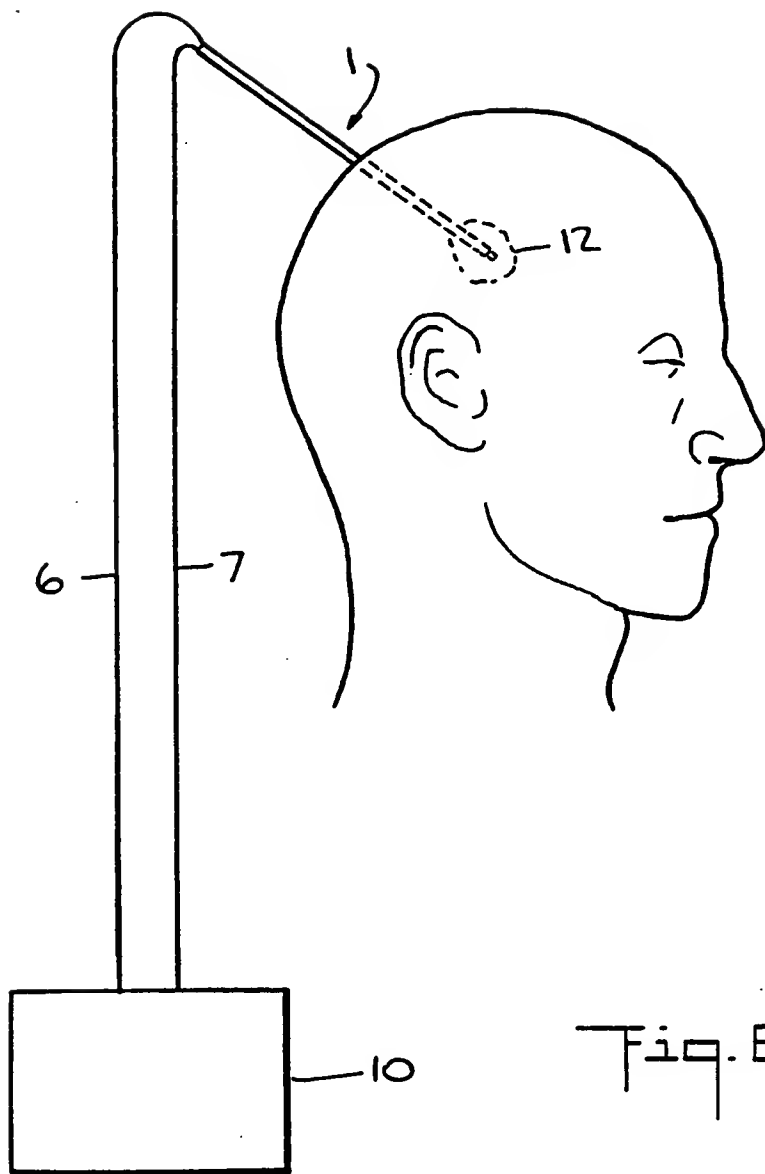


Fig. 6.

# INTERNATIONAL SEARCH REPORT

Int'l Application No  
PCT/IB 94/00424

## A. CLASSIFICATION OF SUBJECT MATTER

A 61 B 17/39

According to International Patent Classification (IPC) or to both national classification and IPC 6

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A 61 B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE, A, 3 609 325 (CERNOVSKY) 24 September 1987 (24.09.87), abstract; fig. 2. --	1
A	US, A, 5 035 695 (WEBER) 30 July 1991 (30.07.91), abstract; fig. 1. --	1
A	US, A, 4 674 499 (PAO) 23 June 1987 (23.06.87), abstract; fig. 2. ----	1

☐ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

### \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search  
10 February 1995

Date of mailing of the international search report  
09.03.95

Name and mailing address of the ISA  
European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,  
Fax (+ 31-70) 340-3016

Authorized officer

NARDAI e.h.